

Please replace the originally filed specification with the new substitute specification of Appendix B.

Applicants voluntarily submit the substitute specification under 37 CFR § 1.125(b).

A marked-up copy of the substitute specification is attached in Appendix C. Further, a statement that the substitute specification includes no new matter is also attached hereto in Appendix D.

**In the Claims:**

Amend claims 14, 49, 50, 51, 52, 53, 61, 62, 63, 65 and 66, as follows<sup>1</sup>:

14. (Once Amended) An adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:
  - (a) a structural papillomavirus polypeptide enclosed by an open reading frame selected from the group consisting of L1-ORF<sub>2</sub> [and] L2-ORF<sub>2</sub> and fragments of any of the foregoing ORFs; and
  - (b) an early papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of: E1-ORF, E2-ORF, E4-ORF, E5-ORF, E6-ORF, E7-ORF and fragments of any of the foregoing ORFs, wherein said early papillomavirus polypeptides or fragments thereof are non-transforming.
49. (Once Amended) An adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:
  - (a) a structural human papillomavirus polypeptide [polypeptide] encoded by an open reading frame selected from the group consisting of L1-ORF and L2-ORF; and
  - (b) an early human papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of: E1-ORF, E2-ORF, E4-ORF, E5-ORF, E6-ORF

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<sup>1</sup> A clean copy of the amended claims is attached in Appendix G hereof, consistent with the requirements of 37 CFR 1.121.

and E7-ORF, wherein said early human papillomavirus polypeptides are non-transforming.

50. (Once Amended) An adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:

- (a) a structural human papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of L1-ORF and L2-ORF; and
- (b) an early human papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of: E1-ORF, E2-ORF, E4-ORF, E5-ORF, E6-ORF and E7-ORF,

wherein said early human papillomavirus polypeptides are non-transforming and the human papillomavirus of (a) and (b) is selected from the group consisting of HPV 16, HPV 18, HPV 33, HPV 35 and HPV 45.

51. (Once Amended) An adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:

- (a) a structural human papillomavirus polypeptide encoded by L1-ORF or a fragment thereof; and
- (b) an early human papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of: E-ORF, E7-ORF and fragments of any of the foregoing ORF, wherein said early human papillomavirus polypeptides are non-transforming.

52. (Once Amended) An adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:

- (a) a structural human papillomavirus polypeptide encoded by an HPV 16 or 18 L1-ORF or a fragment thereof; and

- (b) an early human papillomavirus polypeptide encoded by an HPV 16 or 18 open reading frame selected from the group consisting of E6-ORF, [and] E7-ORF and fragments of any of the foregoing ORFs, wherein said early human papillomavirus polypeptides are non-transforming.
53. (Once Amended) An adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:
- (a) a structural human papillomavirus polypeptide encoded by HPV 16 or 18 L1-ORF; and
- (b) an early human papillomavirus polypeptide encoded by an HPV 16 or 18 open reading frame selected from the group consisting of: E6-ORF and E7-ORF, wherein said early papillomavirus polypeptides are non-transforming.
61. (Once Amended) The vaccine composition of claim [49] 60 further comprising one or more immune system-activating agents.
62. (Once Amended) [The] A vaccine composition comprising: [of claim 49 wherein the vector is provided as a component of a cell.]
- (a) a cell transfected with the vector of claim 14; and
- (b) an auxiliary agent.
63. (Once Amended) The vaccine composition of claim 62 wherein the cell is a tumor or pre-tumor cell [and is associated] infected with a human papillomavirus [infection].
65. (Once Amended) A method for activating an immune system of a subject comprising administering to the subject an adeno-associated virus vector comprising a nucleotide sequence encoding a fusion polypeptide, the fusion polypeptide comprising:

- (a) a structural papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of: L1-ORF, L2-ORF and fragments of any of the foregoing ORFs: and
  - (b) an early papillomavirus polypeptide encoded by an open reading frame selected from the group consisting of: E1-ORF, E2-ORF, E4-ORF, E5-ORF, E6-ORF, E7-ORF and fragments of any of the foregoing ORFs, wherein said early papillomavirus polypeptides are non-transforming.
66. (Once Amended) The method of claim 65 wherein the adeno-associated virus vector [fusion polypeptide] is administered as a component of a vaccine composition.

### **REMARKS**

#### **I. Specification**

A more descriptive Title has been provided. The Abstract and the Specification have been rewritten. Claims 14, 49, 50, 51, 52, 53, 61, 62, 63, 65 and 66 have been rewritten; claims 15 through 48, and 54 through 60, and 64 remain unchanged in the application.

Applicants hereby request reconsideration of the application in view of the foregoing amendments.

In the Office Action of 26 January 2001, the Examiner rejoined the non-elected claims drawn to vaccine compositions and a method for activating the immune system. A more descriptive Title has been provided in view of this action.

The Examiner objected to the form of the Abstract of the Disclosure. The Abstract of the Disclosure has been rewritten in accordance with MPEP § 608.01(b).